Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Cardiovascular and Renal Drugs Advisory Committee
December 7, 2009
Hilton Washington DC North/Gaithersburg,
620 Perry Parkway, Gaithersburg, MD.

Draft AGENDA

8:00 a.m.	Call to Order Introduction of Committee	Emil Paganini, M.D Acting Chair, CRDAC
	Conflict of Interest Statement	Elaine Ferguson, M.S.,R.Ph. Designated Federal Official, CRDAC

The committee will discuss new drug application NDA 21-560, from Novartis Pharmaceuticals Corporation, for everolimus oral tablets, to be used in patients with kidney transplants to prevent rejection of the transplanted kidney.

8:10 a.m.	FDA Introductory Remarks	Renata Albrecht, M.D. Director, Division of Special Pathogen and Transplant Products (DSPTP) Office of Antimicrobial Products (OAP), CDER
8:20 a.m.	<u>Sponsor Presentations: Novartis</u>	
9:50 a.m.	Questions from the Committee to Novartis	
	<u>FDA Presentations</u>	
10:10 a.m.	FDA Efficacy Presentation of NDA 21-560	LaRee Tracy, MS, PhD Statistical Reviewer Division of Biometrics IV, Office of Biostatistics, CDER
10:30 a.m.	Break	
10:45 a.m.	FDA Safety Presentation of NDA 21-560	Ergun Velidedeoglu, MD Medical Officer, DSPTP, OAP, CDER
11:15 a.m.	FDA Exposure Response Presentation of NDA 21-560	Kevin Krudys, PhD Pharmacometrics Reviewer Division of Pharmacometrics, Office of Clinical Pharmacology, CDER
11:30 a.m.	FDA Discussion of Proposed REMS for NDA 21-560	Kathryn O'Connell, MD Medical Officer Division of Risk Management, Office of Biostatistics, CDER Ozlem Belen, MD, MPH Deputy Director for Safety, DSPTP, OAP, CDER
11:50 a.m.	Questions from the Committee to FDA	
12:15 p.m.	<u>Lunch</u>	
1:00 p.m.	Open Public Hearing	

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2:00 p.m.	Questions from the Committee to FDA and Novartis	
2:20 p.m.	Charge to the Committee	Renata Albrecht, M.D. Director, DSPTP, OAP, CDER
2:30 p.m.	Committee Discussion and Answer Questions	
4:00 p.m.	Break	
5:00 p.m.	Adjourn	